Food and Drug Administration

[Docket No. 93N–0457]

Robert Elbert; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) denies Robert Elbert's request for a hearing and issues a final order permanently debarring Robert Elbert, 15000 SW. David Lane, apt. G–61, Lake Oswego, OR 97035, from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on its finding that Mr. Elbert was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the Federal Food, Drug, and Cosmetic Act (the act).

EFFECTIVE DATE: April 3, 1997.

ADDRESSES: Application for termination of debarment to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mary E. Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

On December 12, 1991, the United States District Court for the District of Oregon entered judgment against Mr. Robert Elbert, doing business as Thrifty Drug Store, under a plea of guilty, for one count of knowingly selling, purchasing, and trading drug samples, a Federal felony offense under sections 301(t) of the act (21 U.S.C. 331(t)), 303(b)(1) of the act (21 U.S.C. 333(b)(1)), and 503(c)(1) of the act (21 U.S.C. 353(c)(1)).

In a certified letter received by Mr. Elbert on September 14, 1994, the then-Acting Deputy Commissioner for Operations offered Mr. Elbert an opportunity for a hearing on the agency's proposal to issue an order under section 306(a) of the act (21 U.S.C. 335a(a)) debarring him from providing services in any capacity to a person that has an approved or pending drug product application. FDA based the proposal to debar Mr. Elbert on its finding that he had been convicted of a felony under Federal law for conduct relating to the regulation of a drug product.

The certified letter informed Mr. Elbert that his request for a hearing could not rest upon mere allegations or denials, but must present specific facts showing that there was a genuine and substantial issue of fact requiring a hearing. The letter also notified Mr. Elbert that, if it conclusively appeared from the face of the information and factual analyses in his request for a hearing that there was no genuine and substantial issue of fact which precluded the order of debarment, FDA would enter summary judgment against him and deny his request for a hearing.

In a letter dated October 11, 1994, Mr. Elbert requested a hearing, and in a letter dated November 9, 1994, Mr. Elbert submitted arguments and information in support of his hearing request. In his request for a hearing, Mr. Elbert does not dispute that he was convicted of a felony under Federal law as alleged by FDA. He argues, however, that the agency's proposal to debar him is unconstitutional because a retroactive application of the debarment provisions would violate the U.S. Constitution's ex post facto, due process, and equal protection clauses.

The Deputy Commissioner for Operations has considered Mr. Elbert's arguments and concludes that they are unpersuasive and fail to raise a genuine and substantial issue of fact requiring a hearing. The legal arguments that Mr. Elbert offers do not create a basis for a hearing (see 21 CFR 12.24(b)(1)). Mr. Elbert's arguments are discussed below.

II. Mr. Elbert's Arguments in Support of a Hearing

A. Ex Post Facto Argument

Mr. Elbert first argues that the ex post facto clause of the U.S. Constitution prohibits application of section 306(a)(2) of the act to him because this section was not in effect at the time of Mr. Elbert's criminal conduct. The Generic Drug Enforcement Act (GDEA) of 1992, including section 306(a)(2), was enacted on May 13, 1992, and Mr. Elbert was convicted on December 13, 1991.

An ex post facto law is one that reaches back to punish acts that occurred before enactment of the law or that adds a new punishment to one that was in effect when the crime was committed (*Ex Parte Garland*, 4 Wall. 333, 377, 18 L. Ed. 366 (1866); *Collins* v. *Youngblood*, 497 U.S. 37 (1990)).

Mr. Elbert's claim that application of the mandatory debarment provisions of the act is prohibited by the ex post facto clause is unpersuasive, because the intent of debarment is remedial, not punitive. Congress created the GDEA in response to findings of fraud and corruption in the generic drug industry. Both the language of the GDEA and its legislative history reveal that the purpose of the debarment provisions set forth in the GDEA is ''to restore and ensure the integrity of the abbreviated new drug application (ANDA) approval process and to protect the public health.'' (See section 1, Pub. L. 102–282, GDEA of 1992.)

In a suit challenging a debarment order issued by FDA (58 FR 69368, December 30, 1993), the constitutionality of the debarment provision was upheld against a similar challenge under the ex post facto clause. The reviewing court affirmed the remedial character of debarment:

> Without question, the GDEA serves compelling governmental interests unrelated to punishment. The punitive effects of the GDEA are merely incidental to its overriding purpose to safeguard the integrity of the generic drug industry while protecting public health.

Bae v. *Shalala*, 44 F.3d 489, 493 (7th Cir. 1995); see also, *DiCola* v. *Food and Drug Administration*, 77 F.3d 504 (D.C. Cir. 1996)

Because the intent of the GDEA is remedial rather than punitive, Mr. Elbert's argument that the GDEA violates the ex post facto clause must fail. (See *Bae* v. *Shalala*, 44 F.3d at 496–497.)

B. Due Process and Equal Protection Arguments

Mr. Elbert further argues that an ''ex post facto application of later enacted statutory provisions to prior conduct and convictions of an individual is violative of the express provisions of Amendment V, forbidding that any person be deprived of 'life, liberty, or property without due process of law.''' In his discussion, Mr. Elbert refers to ''the loss of his right and ability to be able to provide services to a person who has an approved or pending drug product application,'' which suggests that he may also be making a ''takings'' argument under the Fifth Amendment.

Mr. Elbert's argument that his due process rights under the Fifth Amendment would be violated by debarment based upon a conviction entered prior to enactment of the GDEA is not persuasive. In *Usery* v. *Turner Elkhorn Mining Co.*, 96 S. Ct. 2882, 2893 (1976), the Court held that the retroactive application of a remedial statute designed to compensate disabled coal miners did not violate the due process clause of the Fifth Amendment. Legislation adjusting rights and burdens is not unlawful even if the effect of the

legislation is to impose a new duty or burden based upon past acts (*id.* (citations omitted)). The Court noted, however, that it would ''hesitate to approve the retrospective imposition of liability on any theory of deterrence * * * or blameworthiness'' (*id.* (citations omitted)). Neither exception applies to debarment.

As discussed above, debarment is remedial, in that it prohibits certain individuals from providing services to a person that has an approved or pending drug product application, in order to meet the legitimate regulatory purpose of restoring the integrity of the drug approval and regulatory process and protecting the public health. In addition, the remedial nature of the GDEA is not diminished simply because the GDEA deters debarred individuals and others from future misconduct (*U. S.* v. *Halper*, 109 S. Ct. 1892, 1901, n.7 (1989); *Bae* v. *Shalala*, 44 F.3d 489, 493 (7th Cir. 1995)). Thus, debarment for a 1991 conviction does not violate Mr. Elbert's due process rights.

With regard to his ''takings'' assertion, Mr. Elbert has not established that his debarment affects any property interest protected by the Fifth Amendment. The expectation of employment is not recognized as a protected property interest under the Fifth Amendment (*Hoopa Valley Tribe* v. *Christie*, 812 F.2d 1097, 1102 (9th Cir. 1986); *Chang* v. *United States*, 859 F.2d 893, 896–897 (Fed. Cir. 1988)). One who voluntarily enters a pervasively regulated industry, such as the pharmaceutical industry, and then violates its regulations, cannot successfully claim that he has a protected property interest when he is no longer entitled to the benefits of that industry (*Erikson* v. *United States*, 67 F.3d 858 (9th Cir. 1995)).

Mr. Elbert further alleges that his debarment denies him ''equal protection of law,'' insofar as persons other than individuals are subject to debarment for acts occurring after enactment of the GDEA, and individuals are subject to debarment for acts and convictions that occurred prior to enactment of the statute as well. This argument also must fail. A statutory classification, such as that made in the GDEA between individuals and persons other than individuals, that neither burdens a fundamental right nor targets a suspect class, will be sustained if the classification bears a rational relationship to a legitimate legislative end (*Romer* v. *Evans*, 116 S. Ct. 1620, 1627 (1996)). The classification will be upheld even if it works to the disadvantage of a particular group (*id*). Moreover, under the rational basis standard of review, Congress need not articulate the rationale supporting its classification (*FCC* v. *Beach*, 113 S. Ct. 2096, 2102 (1993)). The distinction drawn between individuals and persons other than individuals may well have been supported by the fact that Congress had before it evidence from hearings that at least one company that had been found guilty or had admitted to fraud had obtained new management prior to passage of the GDEA (*Generic Drug Enforcement: Hearing on H.R. 2454 Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 102d Cong., 60–61 (1991) (statement of Dee Fensterer, President, Generic Pharmaceutical Industry Association)).

Mr. Elbert does not dispute the fact that he was convicted as alleged by FDA. Under section 306(l)(1)(B) of the act, a conviction includes a guilty plea. The facts underlying Mr. Elbert's conviction are not at issue. Mr. Elbert's legal arguments do not create a basis for a hearing. Accordingly, the Deputy Commissioner for Operations denies Mr. Elbert's request for a hearing.

III. Findings and Order

Therefore, the Deputy Commissioner for Operations, under section 306(a) of the act and under authority delegated to him (21 CFR 5.20), finds that Robert Elbert has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product.

As a result of the foregoing finding, Robert Elbert is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 505, 507, 512, or 802 of the act (21 U.S.C. 355, 357, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective April 3, 1997 (sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Elbert, in any capacity, during his period of debarment, will be subject to a civil money penalty (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Elbert, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any ANDA or abbreviated antibiotic drug application submitted by or with the assistance of Mr. Elbert during his period of debarment.

Mr. Elbert may file an application to attempt to terminate his debarment under section 306(d)(4) of the act. Any such application would be reviewed under the criteria and processes set forth in section 306(d)(4)(C) and (d)(4)(D) of the act. Such an application should be identified with Docket No. 93N–0457 and sent to the Dockets Management Branch (address above). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 17, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–8555 Filed 4–2–97; 8:45 am]

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[Docket No. 94N–0171]

Discovery Experimental and Development, Inc.; Denial of a Hearing and Refusal to Approve a New Drug Application for Deprenyl (Deprenyl Citrate) Gelatin Capsules and Liquid; Final Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Commissioner of Food and Drugs (the Commissioner) is denying a request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) refusing to approve a new drug application (NDA) for Deprenyl (deprenyl citrate) submitted by Discovery Experimental and Development, Inc., 29949 S.R. 54 West, Wesley Chapel, FL 33543 (Discovery). Discovery requested an opportunity for a hearing after the Food and Drug Administration (FDA) issued a proposal to refuse to approve the firm's NDA for Deprenyl. FDA is denying Discovery's request for a hearing because Discovery failed to raise any genuine and substantial issue of fact that would entitle it to such a hearing. FDA bases this order refusing to approve Discovery's product on a finding that, among other deficiencies in the application, there is insufficient information to determine whether Discovery's deprenyl citrate is safe for use or will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling.

EFFECTIVE DATE: April 3, 1997.